UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	04-MD-1603 (SHS)
PURDUE PHARMA L.P., P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS, L.P., and RHODES TECHNOLOGIES, Plaintiffs, -against- VARAM, INC., and KVK-TECH, INC. Defendants.	This document relates to: 10 Civ. 6038 (SHS) OPINION & ORDER

SIDNEY H. STEIN, U.S. District Judge.

This action for patent infringement pursuant to 35 U.S.C. § 271(e) arises from defendant Varam, Inc.'s submission of Abbreviated New Drug Application ("ANDA") number 20-1523 to the Food and Drug Administration through defendant KVK-Tech, Inc. ("KVK") and its staff. Pursuant to 21 U.S.C. § 355(j), defendants sought FDA approval to manufacture and market a generic version of plaintiffs' OxyContin-branded oxycodone hydrochloride extended release tablets before certain patents underlying OxyContin expired.[1] In conjunction with the ANDA, defendants certified that plaintiffs' OxyContin patents are "invalid or will not be infringed" by defendants' proposed generic, within the meaning of 21 U.S.C. § 355(j)(2)(A)(vii)(IV)—termed the "paragraph IV certification." Plaintiffs claim that their patents are valid, that the proposed generic will infringe the patents, and thus that submitting the ANDA constitutes infringement. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit [an ANDA] . . . for a

[1] The contents of the patents at issue are not relevant to the motions the Court decides here.

drug claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . before the expiration of such patent.").

Three motions by defendants are now before the Court. First, KVK has moved pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss the claims against it for lack of subject matter jurisdiction and failure to state a claim for which relief can be granted. Second, Varam has moved pursuant to Rule 12(b)(2) to dismiss the claims against it for lack of personal jurisdiction over it. Third, defendants have jointly moved to transfer this action to the Eastern District of Pennsylvania, or in the alternative stay proceedings pending the resolution of a parallel action filed in the Eastern District of Pennsylvania. For the reasons set forth below, KVK's motion to dismiss the claims against it is considered as a motion for summary judgment and denied, and the Court grants defendants the alternative relief sought in their transfer motion, staying this action, which defers consideration of, and a hearing on, Varam's motion to dismiss for lack of personal jurisdiction.

I. BACKGROUND

As discussed in more detail below, KVK's motion to dismiss for lack of subject matter jurisdiction is more properly considered as alleging that plaintiffs fail to state a claim. Because that Rule 12(b)(6) motion relies on matters outside the pleadings, the Court must consider it as a motion for summary judgment. *See* Fed. R. Civ. P. 12(d). Accordingly, the following facts are drawn from the testimony and documentary evidence that accompanies the parties' submissions.

A. The Parties

1. Plaintiffs

Plaintiffs are three partnerships and a corporation, each of which jointly owns some of the patents that are allegedly essential to OxyContin and to the generic product at issue in the ANDA.

2. KVK-Tech, Inc.

KVK researches, develops, manufactures, distributes, and sells generic pharmaceuticals. (Compl. ¶¶ 8, 11-14; Dep. of Frank Ripp, Jr., dated Oct. 27, 2010 ("Ripp Dep.") at 91:14-92:5, Ex. 2 to Decl. of Thomas Wang dated Jan. 10, 2011 ("Wang Decl."), Dkt. No. 36.) The company has developed at its Pennsylvania facilities approximately ten different generic pharmaceuticals (Ripp Dep. 92:6-21), including a generic immediate-release oxycodone pill (*id.* at 94:17-24). KVK itself manufactures some of the products it has developed, and has distributed and sold all of them throughout the United States. (*Id.* at 95:10-20, 101:3-16.) Frank Ripp, Jr. is KVK's President and Treasurer, overseeing its staff of approximately seventy-five people, largely out of facilities in Newtown, Pennsylvania. (*Id.* at 18:22-19-6, 54:17-22.)

3. Varam, Inc.

Varam's sole shareholder, director, officer and employee, Frank Nekoranik, incorporated the company in Pennsylvania in early February 2010. (Compl. ¶ 6; Dep. of Frank Nekoranik dated Oct. 25, 2010 ("Nekoranik Dep.") at13:12-24-15:6, Ex. 1 to Wang Decl.) Nekoranik created Varam in order to own the extended release oxycodone ANDA (Nekoranik Dep. 87:25-88:5), which he had received from KVK about one week earlier (Wang Decl. Ex. 8). Varam has no other business activity aside from pursuing, through KVK, FDA approval of the ANDA. (Nekoranik Dep. 167:12-16.)

Varam does business at three different addresses: KVK's Newtown offices as its registered address with the Pennsylvania Department of State (Wang Decl. Ex. 3); shared space in the Lahaska, Pennsylvania, offices of Biz-Visors, Inc., a company Ripp owns (Decl. of Frank Nekoranik dated Sept. 2, 2010 at ¶ 5, Dkt. No. 13; Ripp Dep. 28:24-29:3); and Nekoranik's home in Pennsylvania (Nekoranik Dep. at 161:11-164:20). Varam does not pay KVK for the use of its address, and pays only $25 per month for the Biz-Visors space. (*Id.* at 45:23-46:24.)

B. Defendants' Submission of the Abbreviated New Drug Application

The parties essentially agree that KVK and its employees performed all of the work necessary to submit the ANDA except for Nekoranik's review, approval, and signature. In fact, KVK began researching and developing its generic version of extended release oxycodone in 2006, years before Varam existed. (Ripp Dep. 170:24-171:4.) By late 2009, KVK had developed the product, tested it, and drafted the ANDA, but then decided not to move forward with the ANDA. (*Id.* at 175:2-22.) However, KVK subsequently agreed on February 2, 2010, to assign its rights to the draft "ANDA dossier" to Nekoranik in exchange for Nekoranik's promise to pay KVK $1 million "upon marketing approval [by the FDA], sales and distribution by Nekoranik." (Wang Decl. Ex. 8.) In that agreement, KVK also promised to perform all the work necessary to complete the ANDA process. (*Id.*) In other words, KVK gave Nekoranik the draft ANDA free of charge, except that Nekoranik would pay KVK $1 million if, by KVK's efforts, the ANDA were approved. One week later, Nekoranik incorporated Varam, and on February 17, 2010, Nekoranik assigned the same ANDA dossier to Varam in exchange for 100% of Varam's common stock. (Wang Decl. Ex. 9.) Nekoranik has no scientific or technical expertise, and so relied entirely on KVK to conduct the research and assemble the data into the form required for an ANDA. (Nekoranik Dep. 224-25.) After KVK prepared the ANDA, Nekoranik merely "glanced at" the scientific documents (*id.* at 223:6-12) and "reviewed" the overall ANDA application (*id.* at 224:4). He relied on KVK's assurance, through Ripp, that everything was "in order." (*Id.* at 224:17-22).

As originally filed with the FDA in Rockville, Maryland, on March 8, 2010, the ANDA identified Varam as the applicant in some places and KVK as the applicant in others. (*See* Wang Decl. Exs. 14, 16, & 21.) The summary form, FDA Form 356h, lists Varam as the applicant, and KVK as the "authorized U.S. agent," and lists KVK's Newtown facilities as the address for both

Varam and KVK. (Wang Decl. Ex. 21 at 1.) A KVK employee, Ashvin Panchal, signed Form 356h as Varam's agent. (*Id.* at 2.) Nekoranik's cover letter also identifies KVK as the manufacturer and prospective distributor of the drug product, as do the sample labels submitted as part of the ANDA. (Wang Decl. Ex. 19 at 2; Wang Decl. Ex. 23.) Nekoranik further requested that the FDA direct all communications to KVK's office. (Wang Decl. Exs. 19, 21.) After the FDA wrote to Panchal expressing confusion over Varam's role in the ANDA (Wang Decl. Ex. 15), a new Form 356h was submitted on May 19, 2010. That form listed Varam's address as the Biz-Visors office, and Nekoranik himself, rather than Panchal, signed as the responsible official. (Wang Decl. Ex. 22.) KVK personnel have continued to handle all interactions with the FDA regarding the ANDA, pursuant to KVK's agreement with Nekoranik.

C. Procedural History

Based on the ANDA and the accompanying assertion that plaintiffs' patents are invalid or would not be infringed by the proposed generic, plaintiffs filed suit here and simultaneously in the Eastern District of Pennsylvania. *See* Complaint, *Purdue Pharma L.P. v. Varam, Inc.*, No. 10 Civ. 4028 (E.D. Pa. Aug. 10, 2010). After defendants filed the motions now before the Court, the Joint Panel on Multidistrict Litigation transferred the Pennsylvania action to this Court for consolidated pretrial proceedings with *In re OxyContin Antitrust Litigation*, No. 04 MDL 1603. *See* MDL Transfer Order, *Purdue Pharma L.P. v. Varam, Inc.*, No. 11 Civ. 766 (S.D.N.Y. Feb. 3, 2011). In that action, KVK filed a motion to dismiss the claims against it that is materially indistinguishable from the motion to dismiss decided here. While these motions were pending, defendants submitted another ANDA seeking FDA approval of other dosage strengths for essentially the same drug. Purdue responded in 2012 by again filing suit both in this district (*see* Complaint, *Purdue Pharma L.P. v. Varam, Inc.*, No. 12 Civ. 2814) and the Eastern District of Pennsylvania, with the Joint Panel again transferring the latter to this Court over defendant's

objections (*see* Transfer Order, *In re OxyContin Antitrust Litig.*, No. 04 MDL 1603 (S.D.N.Y. Aug. 3, 2012). The latter case is now docketed as *Purdue Pharma L.P. v. Varam, Inc.*, No. 12 Civ. 6047. The parties have filed substantially the same motions, raising the same arguments, in those 2012 cases, and the Court's reasoning here applies with equal force to those motions.

II. DISCUSSION

A. KVK's Liability Pursuant to section 271(e)

KVK moves the Court to dismiss the claims against it, contending that subject matter jurisdiction is lacking and no valid claim can be stated because only Varam—not KVK—actually "submit[ted]" the ANDA within the meaning of 35 U.S.C. § 271(e)(2). As an initial matter, "[s]ection 271(e)(2) is not a jurisdictional statute in the strict sense." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003). The provision creates a cause of action, and hence a case or controversy, for "a highly artificial act of infringement." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Because federal courts generally have jurisdiction over patent infringement claims pursuant to 28 U.S.C. § 1338(a), "section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed." *Allergan*, 324 F.3d at 1330. As the Federal Circuit has recently reiterated, "nothing more" than an allegation of section 271(e)(2) infringement by submitting an ANDA "was required to establish the district court's subject matter jurisdiction pursuant to § 1338(a)." *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012). KVK's motion concerns the proper construction of the infringement cause of action, not the predicate of federal jurisdiction, and so is properly considered as a Rule 12(b)(6) motion. However, plaintiffs and KVK both rely extensively on materials outside the pleadings. Because the Court does not exclude those matters, Rule 12(d) requires that "the motion must be treated as one for summary judgment under Rule 56."

1. Legal Standard

"Summary judgment is appropriate 'if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Lexion Medical, LLC v. Northgate Technologies, Inc.*, 641 F.3d 1352, 1358 (Fed. Cir. 2011) (quoting Fed. R. Civ. P. 56(a)). The Federal Circuit looks to the regional circuit for the summary judgment standard. *MicroStrategy, Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1349 (Fed. Cir. 2005). Thus, this Court must "resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in favor of the party opposing summary judgment." *Kessler v. Westchester Cnty. Dep't of Soc. Servs.*, 461 F.3d 199, 206 (2d Cir. 2006). Nonetheless, the party opposing summary judgment "must do more than simply show that there is some metaphysical doubt as to the material facts, and may not rely on conclusory allegations or unsubstantiated speculation." *Brown v. Eli Lilly & Co.*, 654 F.3d 347 (2d Cir. 2011) (citations and quotation marks omitted).

2. KVK's section 271(e) Submitter Liability

It is generally "*not* . . . an act of infringement to make, use, offer to sell, or sell" patented products if done "*solely* for uses reasonably related to the development and submission" of regulatory filings. 35 U.S.C. § 271(e)(1) (emphasis added). That protection notwithstanding,

> [i]t shall be an act of infringement to submit . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). In sum, generic manufacturers are shielded from liability when they deal in would-be infringing products solely for the purposes of regulatory filings, but they cross the line into unprotected conduct if they submit an ANDA with a paragraph IV certification, *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), claiming the right to sell the generic before a valid patent expires. *See generally Allergan*, 324 F.3d at 1325-27.

The facts of KVK's involvement in the ANDA are not even in material dispute. KVK's staff has taken every relevant action save for the final review, signing and mailing of the ANDA; KVK has researched and developed the product, produced the samples, prepared the ANDA on Varam's behalf, and subsequently communicated about the ANDA with the FDA as Varam's official agent. Moreover, although KVK is neither Varam's parent nor the owner of the ANDA, it holds a direct stake in the ANDA's success. KVK has given the draft ANDA and subsequent labor to Nekoranik for free, subject only to the requirement that Nekoranik pay KVK $1 million if KVK's staff succeeds in getting the ANDA approved and Nekoranik distributes the product. Nekoranik admits he cannot understand the content of the ANDA, and his only role in its submission has been to periodically review and sign papers based on KVK's recommendation.

KVK contends that only one entity can "submit" the ANDA to the FDA and thus incur section 271(e)(2) liability and that said entity must be the named applicant. The statute's text does not define the term, "submit," and neither the Federal Circuit nor the Supreme Court has construed the term in this context. The parties point the Court to two lines of cases in the federal district courts considering whether a party who is not the named applicant on an ANDA can be liable pursuant to section 271(e)(2) for "submit[ting]" the ANDA. KVK relies on two cases where courts found that the manufacturer of the active ingredient for a patented product could not be held liable as a submitter. *See SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 287 F. Supp. 2d 576, 583-85 (E.D. Pa. 2002); *SmithKline Beecham Corp. v. Pentech Pharm., Inc.*, No. 00 C 2855, 2001 U.S. Dist. LEXIS 1935, at *8-*10 (N.D. Ill. Feb. 16, 2001). Plaintiffs distinguish those cases and rely on cases where courts have found that the corporate relative and U.S. agent of the named, foreign applicant could be held liable for submitting the ANDA on the applicant's behalf. *See In re Rosuvastatin Calcium Patent Litig.* ("*Rosuvastatin*"), 719 F. Supp.

2d 388, 396-98 (D. Del. 2010) (collecting cases).[2] Although the facts here are unique, the Court finds the *Rosuvastatin* court's reasoning the most applicable and persuasive.

The active-ingredient manufacturers in *Geneva* and *Pentech* confined their work for the ANDA applicants to a support role distinct from KVK's management of, and financial stake in, the ANDA. In each case, the third parties provided ingredients and information that were used in the ANDA, as specifically protected by section 271(e)(1), but they did not take the extra step of handling the ANDA process for the named applicant as KVK did. Nor did they have the direct financial stake in the ANDA that KVK has. *Cf. Geneva*, 287 F. Supp. 2d at 583-85; *Pentech*, 2001 U.S. Dist. LEXIS 1935, at *8-*10.

This case is much closer to the circumstances that the *Rosuvastatin* court confronted. There, the U.S. agent and the foreign named applicant had largely overlapping ownership, and the agent both signed the forms and listed its address and contact information in the filings. *Id.* at 397. The agent also "intend[ed] to directly benefit from the approval of the ANDA [as] the marketing arm of" the applicant. More importantly, the agent "actively participated in activities related to the ANDA submission." *Id.* The court noted that "[p]arties 'actively involved' in preparing the ANDA are deemed to have 'submitted' the ANDA, regardless of whether they are the named applicant." *Id.* at 396 (quoting *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F.Supp.2d 338, 349 (D. Del. 2009)).

While "active involvement" would suffice under the District of Delaware's test, this Court need not adopt that low a threshold to conclude that KVK can be liable as a submitter. KVK has been more than actively involved in the submission; it has taken every relevant action

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[2] *See also In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 417-18 (D. Del. 2010); *Cephalon, Inc. v. Watson Pharm., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009); *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-307 (D. Md. 2007); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 492-494 (E.D. Va. 2005).

except the final formalities. In these circumstances, to find Varam but not KVK has "submit[ted]" the ANDA pursuant to section 271(e)(2) would be to elevate form over substance.

Accordingly, the Court finds that the record reasonably supports a conclusion that KVK has submitted the ANDA within the meaning of section 271(e)(2), and plaintiffs are not entitled to summary judgment that only Varam—and not KVK—"submitted" the ANDA.

B. Staying this Action

Because the Court has accepted the parallel action filed in the Eastern District of Pennsylvania into this multidistrict litigation for coordinated pretrial proceedings, pursuant to 28 U.S.C. § 1407, transferring this action to that District would be counterproductive at this time. Defendants also request that the Court stay this action, pending resolution of the parallel action. That action is materially indistinguishable from this action, except that Varam concedes personal jurisdiction in Pennsylvania and vigorously contests it here in New York. That difference is decisive as to which action will proceed to the merits of the dispute more efficiently.

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936); *accord TradeWinds Airlines, Inc. v. Soros*, Nos. 08 Civ. 5901 & 10 Civ. 8175, 2011 U.S. Dist. LEXIS 9432, at *7-8 (S.D.N.Y. Feb. 1, 2011). The factors courts consider on a motion to stay include

> "(1) the private interests of the plaintiffs in proceeding expeditiously with the civil litigation as balanced against the prejudice to the plaintiffs if delayed; (2) the private interests of and burden on the defendants; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest." In balancing these factors, "the basic goal is to avoid prejudice."

Soros, 2011 U.S. Dist. LEXIS 9432, at *8 (quotation marks omitted) (quoting *Kappel v. Comfort*, 914 F. Supp. 1056, 1058 (S.D.N.Y. 1996)). In this rare circumstance where two identical actions are proceeding before one judge, a stay of one action for the duration of pretrial

proceedings will not prejudice any party. Unlike in *Landis*, there is no risk here that "a litigant in one cause [will] be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both." 299 U.S. at 255. The parties, claims, and applicable substantive law are identical in the two actions. Given that the Pennsylvania action would still proceed to the merits in this Court, granting defendants' request to stay this action would occasion no delay and so would not prejudice plaintiffs.

Therefore, the interests of the Court, the public, and non-parties determines whether the New York action should be stayed, *see Soros*, 2011 U.S. Dist. LEXIS 9432, at *8, and those interests weigh in favor of a stay. Proceeding with this action, in which Varam contests personal jurisdiction, would require a hearing on the facts relevant to the personal jurisdiction inquiry. Proceeding with the Pennsylvania action would not, and the hearing would prove unnecessary if the matter is resolved on other grounds or settled before trial. Potentially avoiding that hearing conserves the Court's resources and saves the time of any witnesses who might be called to testify—as well as the expense of such a hearing for the parties. Thus, the Court finds that it is within its discretion to stay this action in favor of the essentially identical action already transferred to this Court from the Eastern District of Pennsylvania, No. 11 Civ. 766.

III. CONCLUSION

For the reasons set forth above, KVK's motion to dismiss is construed as a motion for summary judgment and denied. Defendants' motion to transfer this action to the Eastern District of Pennsylvania or in the alternative stay this action is denied to the extent it seeks transfer, but granted to the extent this action is stayed in favor of No. 11 Civ. 766, the essentially identical action already transferred into this multidistrict litigation from the Eastern District of Pennsylvania.

Dated: New York, New York
October 19, 2012

SO ORDERED:

Sidney H. Stein, U.S.D.J.